REMARKS

Applicants submit this Amendment in reply to the Office Action mailed June 4, 2004.

By this Amendment, Applicants have amended claims 1, 31, and 38 to further define the claimed invention. The originally filed specification, drawings, and claims fully support the amendments to claims 1, 31, and 38. No new matter has been introduced.

On pages 2-3 of the Office Action, claims 1-22, 28, 30-35, and 37 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,591,227 to Dinh et al. ("Dinh") in view of U.S. Patent No. 6,206,914 B1 to Soykan et al. ("Soykan"); and claims 23-27, 29, 36, and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dinh in view of Soykan and further in view of U.S. Patent No. 6,605,053 B1 to Kamm et al. ("Kamm"). Applicants respectfully traverse this rejection, and submit that a *prima facie* case of obviousness has not been established. Specifically, the Examiner has not shown that Dinh, Soykan, and Kamm, either individually or in combination, disclose or suggest every aspect of the claimed invention.

For example, independent claim 1 recites a cardiac implant including, among other aspects, "a first therapeutic agent in at least partial covering relation to at least a first portion of one of said exterior surface and said interior surface" and "a second therapeutic agent, different from said first therapeutic agent, in at least partial covering relation to at least a second portion of one of said exterior surface and said interior surface, wherein the first therapeutic agent is not in covering relation to the second portion." In another example, independent claim 31 recites a method for making a

cardiac implant for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel residing at an exterior of the myocardium including, among other aspects, "covering at least a first portion of the scaffold with a first therapeutic agent" and "covering at least a second portion of the scaffold with a second therapeutic agent, different from the first therapeutic agent, wherein the first therapeutic agent does not cover the second portion." In a further example, independent claim 38 recites a method for performing a coronary vessel bypass procedure for supplementing a flow of blood to a coronary vessel including, among other aspects, placing a "conduit including a first therapeutic agent in covering relation to at least a first portion and a second therapeutic agent in covering relation to at least a second portion, wherein the first therapeutic agent is not in covering relation to the second portion." None of Dinh, Soykan, and Kamm, either individually or in combination, discloses or suggests each of the above-quoted deficiencies.

On page 2 of the Office Action, the Examiner wrote that Dinh does not disclose "that the therapeutic substances are arranged in a noncontiguous manner on the stent." Indeed, Dinh does not disclose placing more than one therapeutic substance on the stent at all. Rather, Dinh discloses placing a single therapeutic substance in different layers on a stent. For example, at col. 7, lines 4-44, Dinh discloses various drugs that can be applied independently to different stents, stating that "the rate at which **the drug** is delivered" and "elute **the drug** at a controlled rate." (Emphasis added).

To cure the deficiencies of Dinh, the Examiner relies on Soykan, asserting that "Soykan discloses a stent with an inflow and outflow end with a first and second polymer composition that coats the stent with a therapeutic substance (such as nitric

oxide)," and that the "second polymer composition may coat only portions of the stent, allowing for the noncontiguous application of therapeutic substance along the stent for localized drug therapy."

Soykan discloses an implantable system including a delivery device having eukaryotic cells **capable of producing one or more therapeutic agents** disposed on the delivery device. (Col. 4, lines 23-32; emphasis added). Thus, Soykan does not disclose placing **any** therapeutic agents whatsoever covering **any** portion of the scaffold, and certainly not different therapeutic agents in the manner set forth respectively in each of independent claims 1, 31, and 38. Soykan discloses a first polymer composition covering at least a portion of the stent, and a second polymer composition coating at least a portion of the first polymer composition and eukaryotic cells, however, Soykan does not disclose that either of these polymer compositions include therapeutic agents, and instead discloses that the polymers are compatible with cells and therapeutic agents. (Col. 3, lines 9-14; col. 12, lines 24-26; col. 10, lines 49-50).

Moreover, because Soykan discloses a second polymer composition coating **at least a portion** of the first polymer composition and eukaryotic cells, and that "[o]ne or more surfaces of the stent can be coated with **one or more additional coatings** of a polymer that is the same or different from the second polymer composition," (col. 12, lines 19-50; emphasis added), Soykan does not disclose or suggest "wherein said first therapeutic agent is not in covering relation to the second portion" as set forth in claims 1 and 38, or "wherein said first therapeutic agent does not cover the second portion" as set forth in claim 31.

Furthermore, even assuming *arguendo* that Soykan discloses different therapeutic substances on different portions of the delivery device, there is no motivation to combine this alleged aspect of Soykan with the invention in Dinh, as Dinh teaches against such a configuration. That is, as set forth above, Dinh does not disclose or suggest using more than one therapeutic substance at all. Moreover, even if the invention in Dinh were modified to have different layers containing different therapeutic substances, whether or not the different therapeutic substances were on different portions of the delivery device, such a configuration would likely complicate and/or impede the control of the rate of release of the therapeutic substance (col. 3, lines 22-23 and 35-38; col. 7, lines 10-26). As such, such a modification would impermissibly destroy the purpose of the invention and render it unsatisfactory for its intended purpose. See In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Kamm does not cure the above-noted deficiencies of Dinh and Soykan, and the Examiner does not assert otherwise in the Office Action.

Accordingly, for at least the aforementioned reasons, *prima facie* obviousness has not been established, and Applicants respectfully request withdrawal of the Section 103(a) rejections.

Claims 2-30 and 32-37 depend from one of independent claims 1 and 31, and are therefore allowable for at least the same reasons that each of those respective independent claims is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references, and therefore at least some also are separately patentable.

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the withdrawal of the outstanding rejections, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification and claims in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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